REMARKS

The Office communication sent July 29, 2009 has been received and reviewed. Claims 1-23 stand rejected. Clarifying amendments are to be made to the claims as previously set forth. Support for the amendment to claims 24-28 is found at least at paragraph **[0003]** of the as-filed application. All amendments and claim cancellations are made without prejudice or disclaimer. No new matter has been added. Reconsideration is respectfully requested.

A. 35 U.S.C. § 103(a)

Claims 1, 2, and 4-21 have been rejected under 35 U.S.C. § 103(a) for assertedly being obvious in view of U.S. Patent 5,639,949 to Ligon et al. ("Ligon") and International Publication No. WO 00/61068 to Colin et al. ("Colin"). Applicant traverses the rejection.

To establish a *prima facie* case of obviousness, the prior art itself or "the inferences and creative steps that a person of ordinary skill in the art would [have] employ[ed]" at the time of the invention are to have taught or suggested the claim elements. Additionally, there must have been "a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements" in the manner claimed. *KSR Int'l Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (2007). Furthermore, to establish a *prima facie* case of obviousness there must have been a reasonable expectation of success. M.P.E.P. § 2143.02. Underlying the obvious determination is the fact that statutorily prohibited hindsight cannot be used. *KSR*, 127 82 USPQ2d at 1385.

Applicant respectfully submits that a *prima facie* case of obviousness has not been established against claim 1. At most, the instant rejections propose a combination of elements by picking and choosing disparate elements from the reference, and then combining them, which appears to be a hindsight attempt to gather elements for bringing them together with the benefit of applicants' disclosure.

Specifically, Ligon discloses antipathogenic substances, which it defines as "those having a deleterious effect on the multiplication and growth of *plant* pathogens." *Ligon*, col. 3, lines 10-15. Plant pathogens, however, are clearly different than animal pathogens, as required by the

instant claims. Ligon does teach that macrocyclic lactones are one type of such an antipathogenic substance. *Id.* Ligon also teaches that antipathogenic substances may be isolated and homogenously mixed with other compounds to form antifungal compositions. *Ligon*, col. 17, lines 35-44. These compositions may include other bactericides and fungicides, surfactants, and solvents. *Ligon*, col. 17, lines 45-59. However, nothing in Ligon teaches or suggests that *water-insoluble* macrocyclic lactones and benzimidazoles could be effectively utilized in an aqueous formulation for topical application to an animal. Therefore, it is respectfully submitted that, absent impermissible hindsight, it would not have been obvious to a person of ordinary skill to form an aqueous micellar formulation by combining Ligon with Colin, as Colin does not satisfy the deficiencies of Ligon.

The rejection appears to be based on the assertion that Colin teaches an aqueous formulation because it discloses a "stable liquid veterinary formulation." *Office Action*, p. 2. Applicant respectfully disagrees. Although Colin teaches a liquid, a "liquid" is clearly not synonymous with "aqueous." Specifically, the formulation of Colin comprises *aromatic solvents*, which are liquid, but Colin does not teach or suggest the inclusion of water in any formulation. Therefore, Colin cannot teach or suggest an *aqueous* micellar formulation as claimed.

Moreover, it is respectfully submitted that Colin teaches away from an aqueous formulation. Colin teaches that known anthelmintic formulations are usually suspensions because of the water insoluble nature of triclabendazole. *Colin*, p. 1, lines 23-25. Colin further acknowledges that suspensions are unstable and *less able to be absorbed* when applied as a pour-on. *Colin*, p. 1, line 25 to p. 2, line 2. Consequently, it is respectfully submitted that Colin teaches away from a formulation including *hydrophobic* actives *and* water.

The Office admits that Ligon and Colin do not teach or suggest the claimed concentrations of active ingredients. *Office Action of July 29, 2009*, p. 4. However, the Office relies upon the assertion that "manipulation of relative amounts of formulation components that result in differences in concentration, will not support patentability of subject matter encompassed by the prior art, unless there is evidence indicating that such concentration data are

critical." *Id.* Applicant respectfully submits that, in view of the foregoing analysis, such criteria are irrelevant to the situation at hand.

Applicant's position in this regard is supported by a) the solubility of the actives b) the elevated concentration of active, and c) the volume of formulation that must be administered. Since the active will be more easily systemically absorbed if it is solubilized, the solubility of the active ingredients in the formulation is critical. *As-filed specification*, paragraph **[0010]**. Further, the instant application teaches that commercial pour-on products containing ivermectin require significantly higher administration rates of active ingredient to achieve effective blood concentration. *As-filed specification*, paragraph **[0010]**. Additionally, the specification teaches that the claimed formulation is able to achieve elevated levels of the active ingredients per liter of formulation. *As-filed specification*, paragraph **[0054]**. Absent these elevated levels of active ingredients, a "pour-on" formulation would be unacceptable, due to the large volumes of formulation needed to achieve effective blood concentrations. *As-filed specification*, paragraph **[0016]**.

In addition, claim 1 is not obvious because no reason would have existed to combine Ligon and Colin. There must be a reason that would have prompted a person of ordinary skill in the relevant field to combine the prior art elements in the manner claimed. *KSR Int'l Co. v. Teleflex Inc.* That reason is not apparent in the instant case, absent the inappropriate application of hindsight.

Claim 1 recites an aqueous micellar formulation "for topical application to animals for the control of internal parasites." However, Ligon discloses a formulation for the protection of plants. Applicant respectfully submits that disclosure of a topical *plant* formulation, as in Ligon, would not fairly suggest to a person of ordinary skill, a formulation effective for administering active components *to the bloodstream of an animal.* As discussed in the as-filed specification, one of the major difficulties with topical applications in animals is the low penetration of active through the skin layer. *As-filed specification*, paragraphs **[0003]-[0006]**. However, since the formulations disclosed by Ligon are directed to the protection of plants, it is unclear how the

teachings of Ligon would lead anyone to reasonably expect improved penetration of active through animal skin using the plant formulations taught.

Further, even assuming the formulations of Ligon would be absorbed into the bloodstream of an animal, which assumption applicant questions, the Office has failed to establish that the dose of the actives in the reference formulations would be sufficient for the control of internal parasites. In particular, applicant submits that the solvent based formulations of Ligon and Colin would need to be administered in unacceptably large (and dangerous) volumes to achieve effective blood concentrations of the actives. *As-filed specification*, paragraph **[0016]**. In contrast, the claimed formulation allows for elevated concentrations of the actives within the composition for efficient delivery to the bloodstream.

The rejection appears to be based upon the assertion that each element (*i.e.* actives, solvent, and surfactant) was known and, therefore, the formulation of claim 1 is obvious. Applicant respectfully disagrees, and submits that the mere fact that elements are known ***is not sufficient*** to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. M.P.E.P. § 2143.01(IV). The Office has not identified why a person of ordinary skill would have expected the combination to work by substituting the compounds of Ligon with that of Colin. *See, In re Sernaker* 702 F.2d 989; M.P.E.P §2144. Without a reason to explore alternative components, and without a reason to expect that the substitution might improve skin penetration in an animal, one of ordinary skill would have lacked any motivation to attempt such a combination.

For the foregoing reasons, applicant respectfully requests that the obviousness rejection be withdrawn.

Claims 22 and 23 have been rejected under 35 U.S.C. § 103(a) for assertedly being obvious in view of Ligon, Colin, US Patent 7,026,290 to Domb ("Domb"), and US Patent 5,981,256 to Egelrud et al. ("Egelrud"). Applicant traverses the rejection.

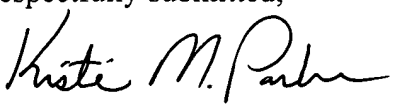
Domb is relied upon for the disclosure of polyoxyethylene (20) sorbitan monolaurate as a surfactant. Egelrud is relied on for the disclosure of diethylene glycol monobutylene ether as a

solvent. Claim 22 is not obvious for substantially the same reasons as discussed previously herein with respect to claim 1. Specifically, Ligon and Colin do not teach or suggest an *aqueous* micellar formulation for *topical application to animals* for the control of *internal* parasites. Further, as previously discussed, applicant respectfully submits that the solvent formulations of Ligon and Colin teach away from the instant *aqueous* formulation. Domb and Egelrud do not provide the missing elements.

Claim 3 is not addressed in the Office Action, however, applicant has presumed it to be rejected in view of Ligon, Colin, and Domb, as applied to claim 22. If this presumption is incorrect, applicants request further clarification in the next Office communication. Domb is apparently relied upon for the disclosure of polyoxyethylene (20) sorbitan monolaurate as a surfactant. Such disclosure does not cure the deficiencies of Ligon and Colin pointed out above, in connection with the rejection of claims 1 and 22. Therefore, claim 3 is believed to be nonobvious.

The application should be in condition for allowance. If, however, questions remain after consideration of the foregoing, the Office is kindly requested to contact applicant's undersigned attorney.

Respectfully submitted,



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